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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872
7590	11/16/2005		EXAMINER	
Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,738

Applicant(s)

WEADOCK ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10, 11, 16-28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 14, 15, 29-33 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/05 has been entered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4, 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Human beings and/or human anatomy are not statutory subject matter and as such cannot be positively set forth as an element(s) of a claimed combination. In Claim 4, "...the first securing means comprises an adhesive disposed between an outer surface of the first vessel..." should read (e.g. --the first securing means comprises an adhesive adapted to be disposed between an outer surface of the first vessel--). The same rejection is applicable to claim 7.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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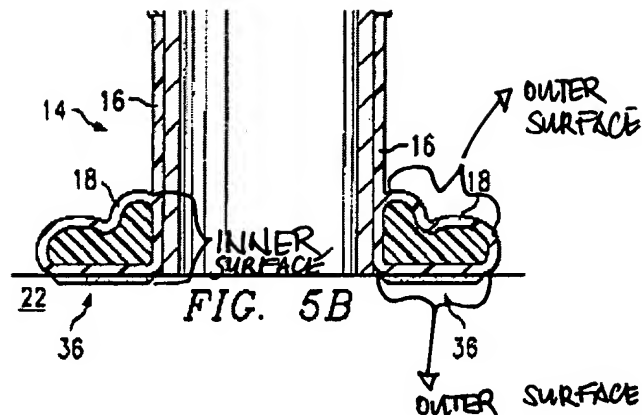
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39, and 41-43 are rejected under 35

U.S.C. 103(a) as being unpatentable over US 6,117,147 to Simpson et al. in view of US 2001/0044631 A1 to Akin et al.

As to claims 1, 2, 4, 5, 7, 29-31, 33, 38, 39, and 41, Simpson discloses a device for creating an end-to-side anastomosis (col. 1, lines 6-9), including a body **18** fabricated from a sponge material. Body **18** is viewed as a sponge because it is formed from a polymer material that is impregnated with a liquid drug (col. 3, lines 17-24), which meets the Applicant's definition (and the common definition) of a sponge. Sponge **18** is secured on two different sides using glue, and therefore has two securing/sealing means (col. 3, lines 27-30). With reference to Figure 5B, sponge **18** is attached to the target vessel at locations **36** (with glue; col. 4, lines 18-23; col. 3, lines 27-35) and is attached to member **16** also with glue (col. 4, lines 15-17).

With regards to the amendments to claim 1, it should be noted that Simpson does teach the body having an outer surface and an inner surface that forms a portion of an opening that is configured to contact an outer surface of the first vessel. This is evident in the attached figure below.



Regarding the limitation in claim 29, "by direct insertion of the portion of the first vessel into the extravascular body," Examiner maintains that Simpson discloses this feature: First vessel **10** is inserted directly into extravascular body **18/16** and touches member **16**, as is evident from Fig. 5B.

Simpson's sponge material is not resorbable, but Akin teaches that the advantage of having a sutureless anastomotic fitting be resorbable is that when it disintegrates, a healed/completely physiologic anastomosis is left behind having no foreign body to contend with the human body's natural functioning (paragraph [0128]). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to form Simpson's sutureless anastomosis disc out of a resorbable material in order to allow the vessel junction to heal normally and to be free from any foreign bodies or substances, as taught by Akin.

As to claim 8, Simpson discloses attaching a graft vessel "to a side wall of a target vessel at an opening in the side wall" with glue (col. 1, lines 6-8). Therefore, the glue will be at and around the opening of the side wall of the target vessel.

As to claim 9, the adhesive is applied to the surface of disk-shaped sponge **18** and will necessarily fill in the interstices of the polymer.

As to claims 14 and 15, Simpson discloses impregnating the polymer with an anastomosis modulating agent (col. 3, lines 18-23).

As to claim 32, Simpson shows holes that are still formed after the second portion of the second vessel is attached to the body.

As to claims 42 and 43, Fig. 6 shows that blood will flow through both of the anastomosed vessels, as Simpson's cuffs are intended to join two vessels together within the human vascular system.

6. Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of Akin et al., and in further view of US 2002/0065545 A1 to Leonhardt et al.

The above combination of Simpson/Akin discloses all of the claimed features of the invention (as detailed above), including gluing between body **18** and graft vessel **10**. However, the modified Simpson invention fails to disclose using a balloon catheter to urge the outer surface of graft vessel against body, compressing the adhesive between them. However, Leonhardt discloses a graft vessel **24** and a body (**10**, aorta) and discloses inserting and expanding a balloon inside of graft vessel in order to urge the outer surface of the graft vessel against body **10** to sandwich the adhesion (glue, 56) therebetween (paragraphs [0027, 0028, 0030, 0060, 0083]; Figs. 1, 9d, 10a). Leonhardt teaches that one should use a balloon catheter in order to secure the outside

surface of graft vessel ("spring means" 26 specifically and member 24 generally) to the interior surface of body (10) (paragraph [0030], last sentence).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a balloon catheter to better secure vessel (10) to body (18), sandwiching adhesive therebetween, as taught by Leonhardt, because a balloon catheter expands the inner member towards the outer member and will cause them to touch and be secured to each other by glue.

Response to Arguments

7. Applicant's arguments filed 9/6/05 have been fully considered but they are not persuasive.

8. Applicant argues that the Simpson reference only teaches an outer surface of cuff 18 being secured to any portion of the vasculature. However, as clearly shown in the attached figure above, one could easily interpret the cuff having an inner surface and an outer surface, wherein the inner surface is the opening within the disk shaped cuff, and wherein the outer surface is the portion that attaches to the aorta.

9. With regards to the Simpson reference allegedly teaching away from using a resorbable material, this argument is not persuasive. Simpson merely states the various known connectors in the art and does not disclose that his reference will not be enabled with a resorbable material. Furthermore, the arguments for desiring a resorbable material between an "intravascular" and "extravascular" device is not persuasive since it would also be beneficial to make a resorbable extravascular device

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as it would allow the device to be absorbed into the body over time without requiring an additional surgery to remove said device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PATENT EXAMINER